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Health informatics — Medical waveform format —

Part 2: Electrocardiography

Informatique de santé — Forme d'onde médicale —

Partie 2: Electrocardiographie

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee 215, *Health informatics*.

This first edition of ISO 22077-2 cancels and replaces ISO/TS 22077-2:2015, which has been technically revised.

The main changes are as follows:

— clarified references in the text for all figures and tables;

— updated clause 3;

— corrected Figure 4, Figure C.1 and Figure C.4;

— deleted the description of "Unique identifier", "Measurement date/time", "Patient information", and "Comment" that are described in ISO 22077-1;

— added and changed the description for some items of Annex B.

— deleted Annex E;

A list of all parts in the ISO 22077 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The standard 12-lead electrocardiography (ECG) is one of the most widely used medical waveforms in clinical sites. In particular, the increased usage of electronic medical records provides the environment in which these ECGs can be accurately utilized; however, to address the therapeutic requirements, ECG use should not be constrained to specific machine types and manufacturers. Furthermore, the various kinds of patient information contained in ECGs that are extensively studied and shared between health care providers.

This document defines the detailed rules for the electrocardiography waveform format that is encoded according to the medical waveform format encoding rules (MFER). Rules for other waveforms such as long-term ECG (Holter ECG), stress ECG, etc. are contained in other MFER documents.

About MFER

Medical waveforms such as ECG, electroencephalography (EEG), and blood pressure waveforms are widely utilized in clinical areas such as physiological examinations, electronic medical records, medical investigations, research, education, etc. Medical waveforms are used in various combinations and document types according to the intended diagnostic purpose. For example, ECG waveforms are utilized extensively in the clinical arena, with resting 12-lead ECG being used the most. A cardiologist typically makes diagnoses using 10 s to 15 s ECG waveform measurements; however, longer periods are sometimes required to recognize heart conditions such as arrhythmia. Also, there are many other methods using ECG such as Holter ECG, physiologic monitoring ECG, stress ECG, intracardiac ECG, vectorcardiography (VCG), EEG with ECG, blood pressure with ECG, sleep polysomnography (PSG), etc. MFER can describe not only ECG for physiological examinations conducted in intensive care unit (ICU) and operating room acute care contexts, but also EEG, respiration waveforms, and pulse.

Implementation

MFER is a specialized representation for medical waveforms that removes unnecessary coded elements ("tags") for waveform description. For example, a standard 12-lead ECG can be described simply only using a common sampling condition and the lead condition, making waveform synchronization and correct lead calculation much easier.

Use with other appropriate standards

It is recommended that MFER only describes medical waveforms. Other information can be described using appropriate standards including HL7®[1] CDA, XML, and DICOM®[2]. For example, clinical reports that include patient demographics, order information, medication, etc. are supported in other standards such as HL7® Clinical Document Architecture (CDA); by including references to MFER information in these documents, implementation for message exchange, networking, database management that includes waveform information becomes simple and easy.

Separation between supplier and consumer of medical waveforms

The MFER specification concentrates on data format instead of paper-based recording. For example, recorded ECG is processed by filter, data alignment and other parameters, so that the ECG waveform can be easily displayed using an application viewer. However, the ECG recordings displayed as images are not as useful for other purposes such as data processing for research investigations. A design goal of MFER is that a waveform is described in raw format with as complete as possible recording detail. When the waveform is used, appropriate processing of the data is supported such as filtering, view alignment, etc. In this way, the medical waveform described in MFER can be used for multiple purposes.

Product capabilities are not limited

1) HL7 is the registered trademark of Health Level Seven International. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

2) DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

Standards often support only a minimum set of requirements, so the expansion of product features can be greatly limited. MFER can describe medical waveform information without constraining the potential features of a product. Also, medical waveform display must be very flexible, and thus MFER has mechanisms supporting not only a machine-readable coded system for abstract data, but also human-readable representations.

The MFER specification supports both present and future product implementations. MFER supports the translation of stored waveform data that was encoded using other standards, enabling harmonization and interoperability. This capability supports not only existing waveform format standards, but it can also be extended to support future formats as well.

Health informatics — Medical waveform format —

Part 2:
Electrocardiography

1 Scope

This document defines the application of medical waveform format encoding rules (MFER) to describe standard electrocardiography waveforms measured in physiological laboratories, hospital wards, clinics, and primary care medical checkups. It covers electrocardiography such as 12-lead, 15-lead, 18-lead, Cabrera lead, Nehb lead, Frank lead, XYZ lead, and exercise tests that are measured by inspection equipment such as electrocardiographs and patient monitors that are compatible with MFER.

Medical waveforms that are not in the scope of this document include Holter ECG, exercise stress ECG, and real-time ECG waveform encoding used for physiological monitors.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 22077-1, *Health informatics — Medical waveform format — Part 1: Encoding rules*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1.1
dominant beat
primary heart beat extracted from typical beats for each lead in a 12-lead ECG

Note 1 to entry: The dominant beat is the beat used for primary measurement and analysis in a 12-lead ECG.

Note 2 to entry: In general, it is the typical beat excepting extrasystole or drifts of baseline.

3.1.2
average beat
beat waveform constructed from the average value of each temporal point in ECG across a number of beats

Note 1 to entry: The average beat is used for the same purpose as the dominant beat.

Note 2 to entry: This is a waveform with the average value of waveforms excluding the abnormal beats for each lead.

3.1.3
median beat
beat waveform constructed from the median value of each temporal point in ECG across a number of beats

Note 1 to entry: The median beat is used for the same purpose as the dominant beat.

Note 2 to entry: This is a waveform with the median value of waveforms excluding the abnormal beats for each lead.

3.1.4
tag
identifier code for a semantic concept

3.2 Abbreviated terms

DICOM®	Digital Imaging and Communications in Medicine
ECG	Electrocardiography
EEG	Electroencephalography
HL7®	Health Level Seven
MFER	Medical waveform Format Encoding Rules
SCP-ECG	Standard communication protocol — Computer-assisted electrocardiography (ISO 41064)
VCG	Vectorcardiography
XML	Extensible Markup Language

4 Encoding format

4.1 Primary description

4.1.1 General

This document provides the encoding of standard 12-lead ECG waveforms. It also supports encodings other than standard 12-lead ECG for use in encoding other ECG waveforms such as Holter, stress test, and real-time physiological monitoring. In addition, along with the ECG waveform encoding, the encoding of waveform recognition information, measurement information, interpretation information, etc. is provided, but these are all optional functions and depend on each implementation concept. For instance, along with MFER-encoded waveforms, interpretation codes or measurement values are described in other standards including HL7® CDA, XML, and DICOM®.

All encoding rules shall apply the requirements described in ISO 22077-1.

In order to make effective use of this document, a MFER conformance statement is provided in Annex A.

4.1.2 Sampling attributes

Sampling attributes including sampling rate and resolution are given in Tables 1 to 4.

4.1.2.1 MWF_IVL (0Bh): Sampling rate

This tag indicates the frequency or sampling interval for the medical waveform is sampled (Table 1).

Table 1 — Sampling rate

MWF_IVL			Data length	Default	Encoding range/remarks	Duplicated definitions
11	0Bh	Unit	1	1 000 Hz	—	Override
		Exponent (10th power)	1		$10^{-128 \text{ to } +127}$	
		Mantissa	≤4		e.g. unsigned 16-bit integer	

The unit can be frequency in hertz, time in seconds, or distance in meters (Table 2).

Table 2 — Sampling rate unit

Unit		Value	Remarks
Frequency	Hz	0	Including power
Time interval	s	1	—

4.1.2.2 MWF_SEN (0Ch): Sampling resolution

This tag indicates the resolution, minimum bits, the medical waveform sampled (generally, digitized) (Table 3).

Table 3 — Sampling resolution

MWF_SEN			Data length	Default	Encoding range/remarks	Duplicated definitions
12	0Ch	Unit	1	See Table 4	—	Override
		Exponent (10th power)	1		$10^{-128 \text{ to } +127}$	
		Mantissa	≤4		e.g. unsigned 16-bit integer	

Table 4 — Sampling units

Unit		Value	Default	Remarks
Voltage	Volt	0	0,000 001 V	—

4.1.3 Frame attributes

4.1.3.1 General

A frame is composed of data blocks, channels and sequences.

4.1.3.2 MWF_BLK (04h): Data block length

This tag indicates the number of data sampled in a block (Table 5).

Table 5 — Data block length

MWF_BLK		Data length	Default	Remarks	Duplicated definitions
04	04h	≤4	1	—	Override

4.1.3.3 MWF_CHN (05h): Number of channels

This tag indicates the number of ECG channels (Table 6). If a previously specified channel attribute is reset to the root definition including Default, the number of channels should be specified before each definition of the channel attribute. The number of channels cannot be specified within the definition of a channel attribute.

Table 6 — Number of channels

MWF_CHN		Data length	Default	Remarks	Duplicated definitions
05	05h	≤4	1	—	Override

4.1.3.4 MWF_SEQ (06h): Number of sequences

This tag indicates the number of sequences (Table 7). If the number of sequences is not designated, it depends on the data block length, the number of channels and the number of waveform data values that are defined for the specified frame.

Table 7 — Number of sequences

MWF_SEQ		Data length	Default	Remarks	Duplicated definitions
06	06h	≤4	Depends on waveform data length	—	Override

4.1.4 Waveform

The waveform class and type, waveform attributes and waveform data are encoded as follows.

4.1.4.1 MWF_WFM (08h): Waveform class

Waveforms such as standard 12-lead ECG and monitoring ECG are grouped based on instruments and purpose, as shown in Table 8.

Table 8 — Waveform class

MWF_WFM		Data length	Default	Remarks	Duplicated definitions
08	08h	2	Non-specific waveform	—	Override
		Str ≤ 32	Waveform description	—	

As a general rule, each type of waveform is described in a separate specification.

For types of waveforms (Table 9), numbers 1 to 49151 (BFFFh) are reserved. Numbers 49152 to 65535 can be used privately, but it is recommended to add these to the MFER specification rather than rely on private extensions.

Table 9 — Standard 12-lead ECG waveforms

Waveform kind	Type	Value	Waveform description	Remarks
Electrocardiography	ECG_STD12	1	Standard 12-lead ECG	Standard 12-lead ECG including general ECG in short-term recording.
	ECG_BEAT	9	QRS beat	In general, one heart beat waveform extracted from standard 12-lead ECG recording. Write comment Average, Median, Dominant
	ECG_DRV	12	Derived lead	Derived ECG from Frank vector leads, EASI lead, etc.

4.1.4.2 MWF_LDN (09h): Waveform attributes (lead name, etc.)

Code and information can be added to the type of waveform (Table 10). Table 11 shows lead name code used in 12-lead ECGs and vector lead ECGs. Because the lead code is encoded by 0 to 127, care should be taken when other standards such as SCP-ECG, etc. are followed. Since part of these code spaces overlap, the present table shall be followed in all MFER applications.

Since in this specification, the code for the lead name is encoded by 127 or less, the codes specified in systems such as SCP-ECG shall require conversion. However, in the present lead code table, leads which are not used in standard 12-lead ECG are defined and, in general, will not need to be replaced.

Table 10 — Definition of waveform attributes

MWF_LDN			Data length	Default	Description range, remarks	Duplicated definition
09	09h	Waveform code	2	Undefined	Data length = 2, if waveform information is encoded	Override
		Waveform information	Str ≤ 32		—	

The present code supports 12-lead electrocardiography waveforms. It is recommended to encode leads using MFER waveform information, rather than those specified in other standards.

In addition, this document extends the 12-lead names for humans to include ECG lead names for animals. When other leads for animals are used, such as CV5RL, CV6LL, CV6LU, and V10, they should be specified by waveform information.

Table 11 — Lead name

Code	Lead	Code	Lead
1	I	—	—
2	II	—	—
3	V1	—	—
4	V2	—	—
5	V3	—	—
6	V4	—	—
7	V5	—	—
8	V6	—	—
9	V7	—	—
10	[b]	—	—
11	V3R	61	III
12	V4R	62	aVR
13	V5R	63	aVL
14	V6R	64	aVF
15	V7R	65	-aVR [a]
16	X	66	V8
17	Y	67	V9
18	Z	68	V8R
19	CC5	69	V9R
20	CM5	70	D(Nehb Dosal)
—	—	71	A(Nehb Anterior)
31	NASA	72	J(Nehb Inferior)
32	CB4	—	—

[a] aVR lead shall not be encoded according to MFER. The users (viewer) should mke a calculation to derive -aVR when required.

[b] Although V2R (10) is defined in other rules such as SCP-ECG, the definition shall not be used in MFER.

Table 11 *(continued)*

Code	Lead	Code	Lead
33	CB5	—	—
34	CB6	—	—

[a] aVR lead shall not be encoded according to MFER. The users (viewer) should mke a calculation to derive -aVR when required.

[b] Although V2R (10) is defined in other rules such as SCP-ECG, the definition shall not be used in MFER.

Code and information can be added to the type of waveform. If a waveform is required to be reconfigured, as in the case of deriving leads III and aVF from leads I and II, the codes should always be specified. The codes should be taken into special consideration as they have a function to specify some processing, as in the case of deriving other limb leads from leads I and II or deriving a waveform based on the lead name. See Annex D for the definition of waveform attributes.

As the lead names are defined depending on the class of waveform, the lead subsets are not called out for each class of waveform in MFER. Thus, caution should be taken in encoding lead names.

For waveform codes, numbers 1 to 49151 (BFFFh) are already reserved. Numbers 49152 to 65535 can be used privately but it is recommended to add these to the MFER specification rather than rely on private extensions.

4.1.4.3 MWF_WAV (1Eh): Waveform data

The entire set of waveform data should be strictly aligned as defined in Frame attributes. If the waveform data are compressed, the data alignment can depend on the compression method, but the waveform data after un-compressing should be aligned according to the definition. Refer to Annex B.

If waveform data are different from what is defined in frame information, they can be discarded depending on application processing. MFER behaviour is undefined in this case.

4.1.5 Channel

4.1.5.1 MWF_ATT (3Fh): Channel attributes (channel definition)

This tag defines the attributes for each channel (see Table 12). Before this definition, the channel number shall be specified using the values in Table 6.

Table 12 — Channel attributes

MWF_ATT		Data length	Default	Remarks	Duplicated definitions
63	3Fh	Depends on definition	—	—	Override

NOTE Channel definition for each channel is encoded with a special context tag of P/C = 1 and tag number of 1Fh. That is, the type number is P/C + tag number encoded with 3Fh and identifies the attribute of the relevant channel.

For the tag of the channel attribute definition, context mode is selected with P/C (bit 6 = 1) (Figure 1).

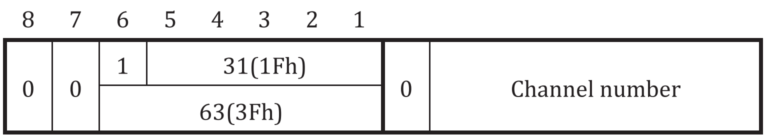


Figure 1 — Number of channel

The data length includes all the range of the channel attribute definition (Figure 2).

Tag		Data length	Group of definition									
3Fh	Channel number	All definition	Channel attribute			Channel attribute			—	Channel attribute		
			T	L	V	T	L	V	—	T	L	V

Figure 2 — Definition of channel attributes

The channel attribute definition can be described with the indefinite length (Figure 3).

Tag		Data length	Group of definition								
3Fh	Channel number	80h	Channel attribute			Channel attribute			—	End-of-contents	
			T	L	V	T	L	V	—	00	00

Figure 3 — Definition of channel attributes with indefinite length

4.2 Data alignment

This document supports many ECG alignment styles according to Annex B, allowing for complicated alignment formats that could result in processing issues. It is recommended that formats be simplified as much as possible in order to maximize interoperability.

4.3 Abstract waveform

This example is in principle the same as the 12-lead ECG, but one heartbeat of P-QRS-T is extracted and expressed (see Figure 4). The abstract waveform is processed in three ways: extraction as dominant beat, average beat and median beat. These depend on the system concept and measurement method. The abstract waveform should be clearly stipulated in implementation specifications, but all leads can be encoded by abstract waveform of MFER.

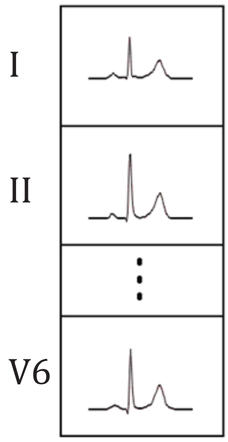


Figure 4 — Abstract waveform

4.4 Lead calculation

Recent electrocardiographs frequently adopt systems to record limb leads by Leads I and II only. In such event, Leads III, aVR, aVL, and aVF shall be calculated. Derivation shall be performed by the following operations (see Table 13, Table 14, Table 15):

In implementing lead calculation, thorough consideration shall be given to aspects such as A/D conversion method, phase deviation or electrode disconnection, and care must be practiced to prevent occurrence of arithmetic waveform distortion.

Table 13 — Lead calculation operation table (calculation from leads I and II)

Lead name	Calculation operation	Computation (right arm potential R; left arm potential L, left foot potential F)
III	II – I	III = F–L = (F–R)– (L–R) where, II = F - R and I = L - R
aVR	–(I + II)/2	aVR = R–(L+F)/2 = {(R–L)+(R–F)}/2
aVL	I – II/2	aVL = L–(R+F)/2 = {(L–R)+(L–F)}/2 = (I–III)/2 = I–II/2
aVF	II – I/2	aVF = F–(R+L)/2 = {(F–R)+(F–L)}/2 = (II+III)/2 = II–I/2
-aVR	Inverted aVR	

Table 14 — Lead calculation operation table (calculation from leads I and III)

Lead name	Calculation operation	Computation (right arm potential R; left arm potential L, left foot potential F)
II	III+ I	II = F–R = (F–L)+ (L–R) where, III = F - L and I = L - R
aVR	– I – III/2	aVR = R–(L+F)/2 = {(R–L)+(R–F)}/2 = {–I–(III+I)}/2 = –I–III/2
aVL	(I – III)/2	aVL = L–(R+F)/2 = {(L–R)+(L–F)}/2 = (I–III)/2
aVF	III + I/2	aVF = F–(R+L)/2 = {(F–R)+(F–L)}/2 = {(III+I)+III}/2 = III+I/2
-aVR	Inverted aVR	

Table 15 — Lead calculation operation table (calculation from leads II and III)

Lead name	Calculation operation	Computation (right arm potential R; left arm potential L, left foot potential F)
I	II – III	I = L–R = (F–R)– (F–L) where, II = F - R and III = F - L
aVR	–II + III/2	aVR = R–(L+F)/2 = {(R–L)+(R–F)}/2 = {– (II–III) –II }/2 = –II+III/2
aVL	–III + II/2	aVL = L–(R+F)/2 = {(L–R)+(L–F)}/2 = {(II–III) –III}/2 = –III+II/2
aVF	(II +III)/2	aVF = F–(R+L)/2 = {(F–R)+(F–L)}/2 = (II+III)/2
-aVR	Inverted aVR	

Sampled ECG data for all leads shall be completely synchronized.

4.5 Filter information

When filter information is described in MFER, it is classified in two cases: filter-processed data and non-filtered use information.

4.5.1 Description of filter-processed data

Description is made on the filter information processed for the data described by MFER (see Tables 16 and 17).

Table 16 — Filter information

MWF_FLT		Data length	Duplicated definitions
17	11h	Str < 256	Possible

Table 17 — Filter description example

Filter function	Abbreviation	Example	Meaning
Filter information only	None	Hum filter ON	Hum filter (characteristics, etc. not specified) used.
High-frequency pass filter	HPF	HPF = 0,05	Indefinite characteristics 0,05 Hz low frequency cutoff (high-pass) filter used.
Low-frequency pas filter	LPF	LPF = 150^secondary Butterworth filter	Butterworth secondary characteristics 150 Hz high frequency cutoff (low-pass) filter used.
Band elimination filter	BEF	BEF = 50^Hum filter	50 Hz Hum filter used. Cutoff characteristics not known.

In ECG, high-pass (low frequency cutoff) filter is frequently described by the time constant, but in MFER, it is recommended to describe it by frequency. For example, the low frequency cutoff filter, which has the primary Butterworth characteristics shown by frequently used CR, is described by the following:

By High-Pass Filter = $1/\omega T$, the lower cutoff frequency of time constant of 3 s is described by $1/(2\pi \times 3\ \text{s}) \approx 0{,}05$ Hz.

4.5.2 Description of filter use information

In this case, MFER ECG data has not been subject to filter processing, and the fact that a specific filter is used is stipulated only. For example, this information can be used to indicate that the ECG was measured by an electrocardiograph, printed on recording paper underwent the relevant filter processing and can be utilized for diagnosis.

5 Measurement information

5.1 General

Out of information generated during measuring ECG, information that would exert effect on the authenticity of ECG and validity of waveforms is encoded. For example, it is possible to encode waveform display information and power supply frequency that do not exert effect on the generating of ECG waveform measurement but that are required to reproduce the condition at the time of measurement. The descriptions in this clause should be implemented in accordance with appropriate standards including HL7® CDA, XML, and DICOM®.

Refer to Annex C.

5.2 Measurement time (classification point)

The measurement time (classification point) is encoded by MWF_EVT format (Table 18).

Table 18 — Event

MWF_EVT			Data length	Encoding range/remarks	Duplicated definitions
65	41h	Event code	2		Possible
		Starting time (point)	4	Number of samples acquired at the sampling interval defined in the root definition	
		Duration	4		
		Event information	Str < 256		

When the recognition point of ECG waveform is shown (Figure C.1), it is encoded by the event code.

When the recognition point in an ECG waveform is encoded by the root definition, it applies to all leads. When it is in a channel definition (each channel), the recognition point shall only apply to that channel.

By specifying the lead inside the channel definition, the recognition point of each lead can be encoded. If the waveform is not encoded using MFER, then the lead should be specified in the channel definition.

5.3 Measurement value

The measurement value is encoded by MWF_VAL (Table 19).

Table 19 — Measurement value

MWF_VAL			Data length	Encoding range/remarks	Duplicated definition
66	42h	Value code	2		Multiple definitions available
		Time point	4	Number of data values sampled is encoded.	
		Value	Str ≤ 32	Value is encoded with a character string with unit (“^”).	

5.4 Measurement information classification

5.4.1 Observation event

Events that have actually occurred, such as clinical observations, can be encoded by the use of MWF_EVT (Table 20).

Table 20 — Event information

MWF_EVT			Data length	Encoding range/remarks	Duplicated definition
65	41h	Event code	2		Possible
		Starting time (point)	4	Number of data values acquired at the sampling interval defined in the root definition.	
		Duration	4		
		Event information	Str < 256		

5.4.2 Waveform ancillary information

Information that possibly exert an effect on the waveform, such as power supply frequency, shall be encoded using MWF_INF (Table 21).

Table 21 — Waveform ancillary information

MWF_INF			Data length	Encoding range/remarks	Duplicated definitions
21	15h	Ancillary information code	2		Possible
		Starting time (point)	4	Number of data values acquired at the sampling interval defined in the root definition.	
		Duration	4		
		Waveform information	Str < 256		

5.4.3 Recording/display condition

"MWF_CND" is for describing an electrocardiograph recording and screen image conditions such as lead name and recording pattern. Doctors diagnose not only by an electrocardiograph recording and screen image, but also by displaying ECGs in EMR systems. An electrocardiograph recording and screen image can be reproduced using "MWF_CND".

Table 22 — Recording/display, etc. information

MWF_CND			Data length	Remarks	Duplicated definitions
68	44h	Recording/display condition	2		Possible
		Description code 1	2		
		Description code 2	2		
		Starting point	4		
		Duration	4		
		Descriptive information	Str < 256		

5.4.3.1 Waveform display example

Recording lead combinations used when ECG is measured are encoded by MWF_CND (Table 22):

Tag: MWF_CND

Recording/display condition: MWF_ECG_LEADS (65030)

Description code 1: channel No. 1 –

Description code 2: lead name

Starting point: record starting point

Duration: Relevant recording time

5.4.3.2 Recording sensitivity display example

The recording sensitivity used at the time of recording is encoded.

5.5 Power supply frequency

The power supply frequency can be encoded. In general, the electrocardiograph has an AC interference elimination filter, but recording without filter processing and adding encoding of power supply frequency can eliminate AC interference by secondary processing.

5.6 Electrode condition

This can be specified when electrodes are disconnected. In particular, in the event that lead composition is performed, the derivation operation will not be performed accurately, a possible situation that should be thoroughly taken into account in implementation.

5.7 Calibration waveform

Encoding can be performed when the calibrated waveform is implemented.

5.8 Artefact contamination

This code can be used to indicate that artefact and noise get mixed at the time of measuring ECG.

5.9 Automatic interpretation code, etc.

The Interpretation code is used for an automatic analysis system, but in the event that this function can be represented using another protocol such as HL7®, it that protocol should be used.

5.9.1 MFER interpretation code and heart beat code encoding rules

Interpretation statements code and beat annotation can be encoded using the event tag (see Table 23).

Table 23 — Automatic interpretation code

MWF_EVT			Data length	Encoding range/remarks	Duplicated definitions
65	41h	Interpretation statements code	2	See Figure 5	Possible
		Starting time (point)	4	Number of data values acquired at the sampling interval defined in the root definition.	
		Duration	4		
		Interpretation statements de-scrip-tive informa-tion	Str < 256		

16	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1
0	0	0	Interpretations statements code											Question	

Figure 5 — Composition of interpretation statements code

The interpretation statements code is composed with 128 - 8191.

The question bit code means:

0: Undesignated (finalization or designation is not particularly needed)

1: In the event that there is little possibility of rendering an opinion

2: When there is any question

3: When there is strong question

and is able to designate the following supplementation:

a) Interpretation code

When the applicable opinion is encoded throughout the whole frame, definition shall be made in the root definition region. In the event that no event information is used, both starting time and duration are not used. In the case that event information is used, “zero” shall be employed for both starting time and duration.

b) Waveform classification for each heart beat

The time of the position of the applicable heart beat shall be designated as the starting time and no duration time is used. When the event information is used, the duration shall be set to “zero” and the event information is used.

c) Waveform classification within the period

For example, transient bundle branch block, etc. are encoded, using the starting time and duration, the relevant regional time shall be specified.

d) When waveform classification is encoded simultaneously with event information, event code and event information can be specified at the same time, or the event code = 0 and the event information can be encoded.

Annex A
(informative)

MFER Conformance statement

Each implementer should provide a specification sheet of their MFER waveform format using the conformance statement in Table A.1. Use of non-default values should be identified clearly. If the extension capabilities of the MFER description are used, an additional sheet with these optional extensions should also be provided.

Table A.1 — Conformance statement template

MFER specification			**Frame**	/	**Ver.**	
Producer	Manufacturer		Date		Model	
	Author		Edited date			
Waveform title			Specification			
Preamble			Endianity	• Default(big endian) • Big endian • Little endian		
Version	..	Character				
Sampling attributes	Sampling rate	Unit		Exponent	Mantissa	
	Sampling resolution	Unit		Exponent	Mantissa	
Data type	• Default • ( )	NULL	• Not used • ( )	Offset value	• Not used • ( )	
Frame number		Block		Channel	Sequence	

Channel No.	**Lead or Waveform**	**Condition**	**Remarks**
Note			

Annex B
(informative)

Waveform alignment

NOTE In this section, the term "channel" is used differently from the "channel attributes" of the frame referred to in MFER Part 1 according to traditional electrocardiography. Be careful to avoid any misunderstanding in its interpretation. For example, a 3-channel ECG has a different meaning from the channel attributes of the MFER frame.

B.1 1-channel ECG

B.1.1 General

This model describes the oldest type of 1-channel electrocardiograph, where an ECG is recorded by measuring over one lead. For each lead, the frame is encoded and the waveform length is variable (Figure B.1). Waveforms can be viewed in chronological order, but the format should be properly changed for display or recording as is the case with the realignment to 3x4 leads of Figure B.2. This encoding is old-fashioned as an electrocardiograph but is still popularly used for a biological information monitor, for example.

B.1.2 1-channel ECG recording

ECG is recorded frame by frame and relevant lead waveform is not ensured of temporal continuation. Consequently, time-phase that bestrides leads, for example, RR interval, has no meaning.

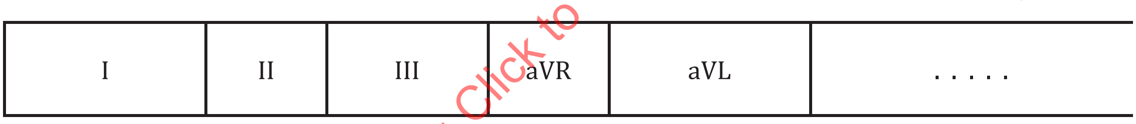


Figure B.1 — 1-channel ECG

B.1.3 3-channel realignment of waveforms recorded in 1-channel ECG

In this case, 1-lead ECGs that are shown in 1-channel ECG of Figure B.1 are realigned into 3x4 leads (Figure B.2). In such events, the waveform phase between channels is not compensated and there is no synchronism in each heartbeat.

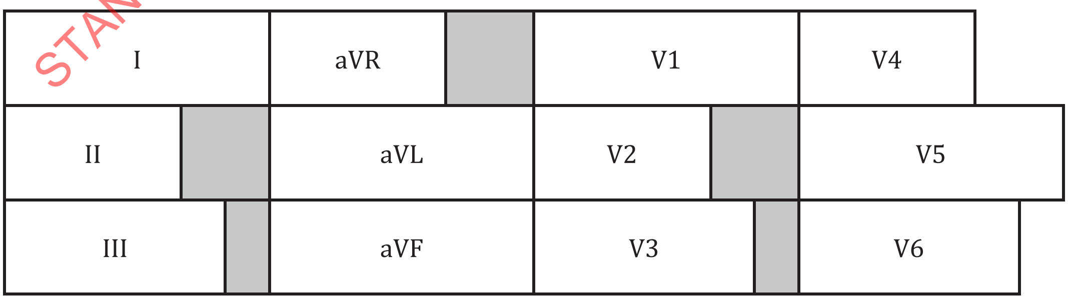


Figure B.2 — Realignment to 3x4 leads

B.1.4 6-channel realignment of waveforms recorded in 1-channel ECG

This is a case in which 1-lead ECG shown in 1-channel ECG of Figure B.1 is realigned into 6x2 leads (Figure B.3). In such event, the waveform phase between channels is not compensated and there is no synchronism in each heartbeat.

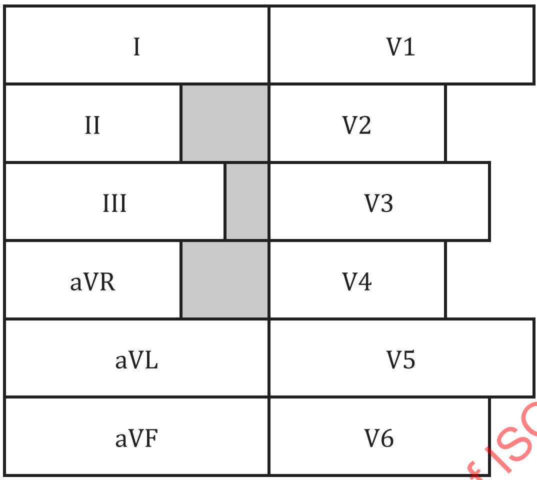


Figure B.3 — Realignment to 6x2 leads

B.2 Multichannel ECG

This is a model to represent 2-channel, 3-channel, and other ECGs. No synchronism is achieved in waveform phases between groups.

This information does not indicate the actual recording image such as multiplex mode recording, alternate mode recording, as specified in ISO 22077-1.

B.2.1 3-channel ECG

This model assumes 3-channel recording electrocardiograph (Figure B.4). In this model, there is no time synchronism between groups, for example, I, II, and III and aVR, aVL, and aVF groups.

I	aVR	V1	V4
II	aVL	V2	V5
III	aVF	V3	V6

Figure B.4 — 3-channel ECG

B.2.2 Realignment of 3-channel ECG to 6x2 lead ECG

This is a case in which 3-lead ECG shown in 3-channel ECG of Figure B.4 is realigned into 6x2 leads (Figure B.5). In this case, too, there is no time synchronism between groups, either, same as B.2.1.

I	V1
II	V2
III	V3
aVR	V4
aVL	V5
aVF	V6

Figure B.5 — 6x2 lead realignment

B.2.3 In case where calculating leads are used

It is possible to calculate from Limb Lead I and Lead II by other limb lead composition. The limb leads in Figure B.6 are derived from Lead I and Lead II in Figure B.5.

I	V1
II	V2
III or calculated III	V3
calculated aVR	V4
calculated aVL	V5
calculated aVF	V6

Figure B.6 — Realignment of calculated 6x2 leads

B.3 Multichannel simultaneous recording ECG

In general, 8 leads of I, II, V1, V2, V3, V4, V5, and V6 are encoded by MFER to exchange and retain messages, and when they are used for display or recording, other limb leads are calculated by derivation (see 4.4). In this format, besides 8 leads, a method of simultaneously recording 9 leads (I, II, III, V1, V2, V3, V4, V5, and V6 are simultaneously recorded and aVR, aVL, and aVF are arithmetically calculated) and 12 leads (I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6) is used. This information does not indicate actual recording images such as multiplex recording, alternate mode recording, etc. specified in ISO 22077-1.

NOTE Besides deriving other leads calculating from two leads of I and II, other leads can be derived from Leads I and III or Leads II and III (see Table 13).

B.3.1 8-lead ECG

The ECG consists of 2 channels limb leads (in general, Leads I and II) and 6 channels chest leads from V1 through V6 (Figure B.7). The remaining limb leads (III, aVR, aVL, and aVF) can be derived by calculations (refer to Table 13). However, limb leads are able to be used in other combinations, for example, combinations of Leads II and III and Leads III and I (see Table 13).

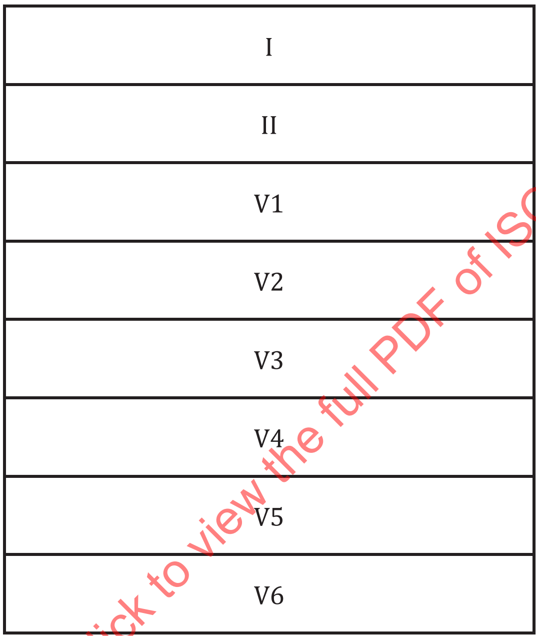


Figure B.7 — 8-lead ECG

B.3.2 9-lead ECG

The ECG consists of 3 channels limb leads (Leads I, II and III) and 6 channels chest leads from V1 through V6 (Figure B.8). It can prevent the accident that all the limb lead waveforms cannot be recorded even if one electrode of the limb lead is disconnected.

I
II
III
V1
V2
V3
V4
V5
V6

Figure B.8 — 9-lead ECG

B.3.3 12-lead simultaneous ECG

All 12-lead ECGs are simultaneously recorded. (Figure B.9)

I
II
III
aVR
aVL
aVF
V1
V2
V3
V4
V5
V6

Figure B.9 — 12-lead ECG

B.3.4 12-lead full synchronizing ECG at the time of use

In ECGs encoded in B.3.1 and B.3.2, remaining Leads III, aVR, aVL, and aVF are derived by calculations in Table 13. (Figure B.10)

I
II
calculated III
calculated aVR
calculated aVL
calculated aVF
V1
V2
V3
V4
V5
V6

Figure B.10 — Calculated 12-lead synchronization display

B.3.5 6x2 lead composition synchronization ECG

In this display, there is a method to display all leads fully synchronized and a method to display temporal misalignment, that is, to display Lead I (group) followed by Lead V1 (group). In the case of Figure B.11, the other limb leads (III, aVR, aVL, and aVF) are derived by calculation from encoded lead I and II. Others use encoded lead II and III, others use encoded lead I and III.

I	V1
II	V2
calculated III	V3
calculated aVR	V4
calculated aVL	V5
calculated aVF	V6

Figure B.11 — Calculation type 6x2 leads

B.3.6 3x4+1 leads are displayed by calculated leads

Figure B.12 shows one lead simultaneously for reference. In this display, there is a method to display all leads fully synchronized and a method to display temporal misalignment, that is, to display Lead I (group) followed by Lead aVR (group), Lead V1 (group) and Lead V4 (group).

I	calculated aVR	V1	V4
II	calculated aVL	V2	V5
calculated III	calculated aVF	V3	V6
II			

Figure B.12 — 3x4+1 leads

B.3.7 Lead-reassigned 12-lead ECG display 1

Figure B.13 shows to reassign 12-lead ECG waveforms in the order of vector with directions taken into account.

calculated aVL
I
calculated (-aVR)
II
calculated aVF
calculated III
V1
V2
V3
V4
V5
V6

Figure B.13 — Reassigned 12-lead ECG

B.3.8 6x2 lead composition synchronization ECG

Figure B.14 shows to reassign 12-lead ECG waveforms in the order of vector with directions taken into account. In this display, there is a method to display all leads fully synchronized and a method to display temporal misalignment, that is, to display Lead I (group) followed by Lead V1 (group). In this example, the other limb leads (III, aVR, aVL, and aVF) are derived by calculation from encoded lead I and II. Others use encoded lead II and III, others use encoded lead I and III.

calculated aVL	V1
I	V2
calculated (-aVR)	V3
II	V4
calculated aVF	V5
calculated III	V6

Figure B.14 — Lead-reassigned 12-lead ECG display 6x2 display

B.3.9 Free format

In addition, this format describes an optional time with optional lead combinations. In this example, optional combinations of a total of 3 leads of Lead II, Lead V1, and Lead aVF are recorded for an optional time (Figure B.15).

II
V1
aVF

Figure B.15 — Free format

B.3.10 Extended lead

When extended lead is lead-designated, extended display is enabled by the above display and the display that conforms to multichannel ECG (possibility of failure of time-phase coincidence).

Figure B.16 shows an example of adding ECG for dextrocardia.

I	V1	V2 (V1R)
II	V2	V1 (V2R)
calculated III	V3	V3R
calculated aVR	V4	V4R
calculated aVL	V5	V5R
calculated aVF	V6	V6R

Figure B.16 — Extended lead example

Figure B.17 shows an example of adding ECG of posterior lead.

I	V1	—
II	V2	—
calculaed III	V3	—
calculated aVR	V4	V7
calculated aVL	V5	V8
Lead aVF	V6	V9

Figure B.17 — Extended lead 1

Figure B.18 shows an example of adding ECG of 3 right sided chest leads.

I	V1	—
II	V2	—
calculated III	V3	—
calculated aVR	V4	V3R
calculated aVL	V5	V4R
calculated aVF	V6	V5R

Figure B.18 — Extended lead 2

Annex C
(informative)

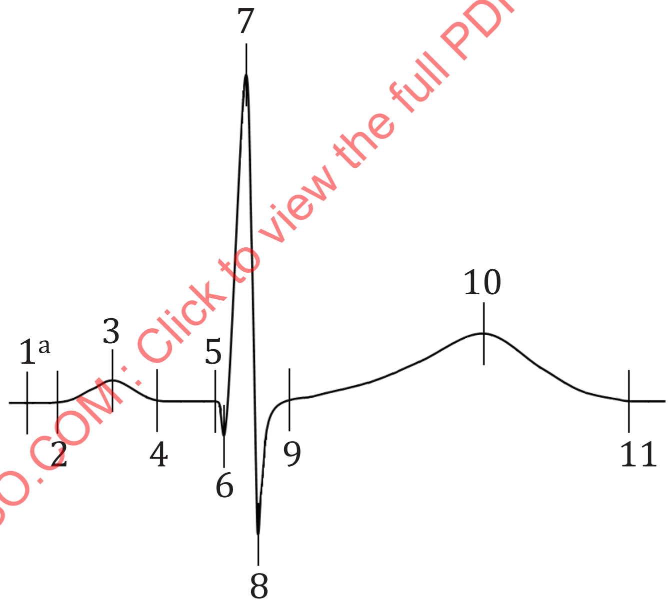
Encoding of waveform recognition point and measurement values

C.1 General

Waveform recognition points (classification point) can be encoded with event tag (MWF_EVT), which is categorized as Level 2 as defined in ISO 22077-1.

C.2 Waveform recognition point

The ECG waveform recognition points are shown in Figure C.1, and each point is encoded with the event tag of MFER coding. In the case that the recognition point is encoded in the root definition, the recognition points affect all leads of the beat. On the other hand, if the recognition points are in the channel definition, they only apply to beats in that channel.



Key

1 fiducial point of ECG wave
2 beginning of P wave
3 peak of P wave
4 end of P wave
5 beginning of QRS complex
6 peak of Q wave
7 peak of R wave
8 peak of S wave
9 end of QRS complex
10 peak of T wave
11 end of T wave

[a] The fiducial point can be QRS-onset or any other point of the QRS complex.

Figure C.1 — Waveform recognition point

C.3 Encoding for recognition point

The waveform identification point is encoded with an event tag (MWF_EVT) (Table C.1).

The episode code such as P wave, QRS, etc. is represented on the waveform recognition code of the MWF_EVT.

The start point of the episode such as P onset, QRS onset, etc. is described on the starting time position of the MWF_EVT, In the case of a single point representation such as the peak point, only the staring time position is used. If this is the case and supplement information is used, the duration shall be zero.

The end point is described by start point and duration, namely the end point is presented by start point + duration period. If there is specific information for the recognition point, the information can be described on the supplementary part in a text string.

Table C.1 — Event

<table>
<tr><th colspan="3">MWF_EVT</th><th>Data length</th><th>Encoding range/remarks</th><th>Duplicated definitions</th></tr>
<tr><td rowspan="4">65</td><td rowspan="4">41h</td><td>Event code</td><td>2</td><td>Waveform recognition point code</td><td rowspan="4">Possible</td></tr>
<tr><td>Starting time (point)</td><td>4</td><td rowspan="2">Number of data values acquired at the sampling interval defined in the root definition</td></tr>
<tr><td>Duration</td><td>4</td></tr>
<tr><td>Interpretation statements descriptive information</td><td>Str < 256</td><td></td></tr>
</table>

<table>
<tr><td>16</td><td>15</td><td>14</td><td>13</td><td>12</td><td>11</td><td>10</td><td>9</td><td>8</td><td>7</td><td>6</td><td>5</td><td>4</td><td>3</td><td>2</td><td>1</td></tr>
<tr><td colspan="7">Waveform recognition point code</td><td>0</td><td>0</td><td colspan="7">Lead code</td></tr>
</table>

Figure C.2 — Waveform recognition point code bit

Lead code designation can be encoded as channel information when the channel coincides with the entity but in the 12-lead ECG, it is encoded by Figure C.2.

C.4 Group definition

When the waveform recognition points are identified as the same heart beat such as a P-QRST-T, the beat is indicated using bracketing by group definition (MWF_SET) (Table C.2). Since this tag is P/C = 1(bit 6), the group definition implies the context mode.

Table C.2 — Group definition

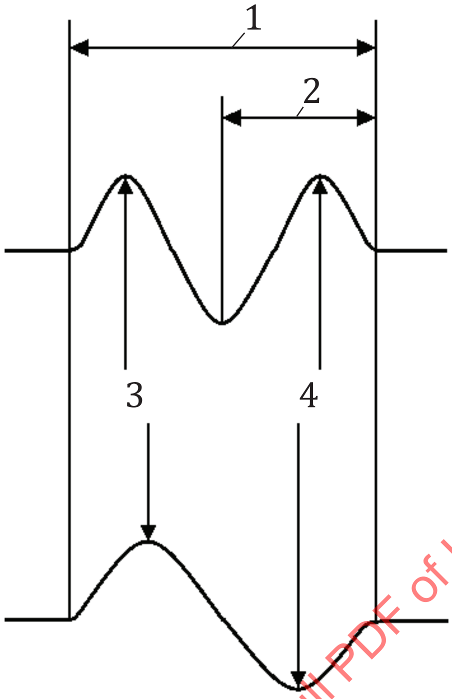
<table>
<tr><th colspan="2">MWF_SET</th><th>Data length</th><th>Default</th><th>Remarks</th><th>Duplicated definitions</th></tr>
<tr><td>103</td><td>67h</td><td>Depends on definition</td><td></td><td></td><td>Not possible within scope</td></tr>
</table>

The group definition means that all recognition points are related to each other. For example, a P wave activity generates the following QRS contraction, and QRS and T wave are same beat phenomenon. Therefore, when some events should be described at same time, these events can be grouped as same beat (see Figure C.3).

<table>
<tr><td colspan="4">MWF_SET</td></tr>
<tr><td></td><td>P wave</td><td>QRS</td><td>T wave</td></tr>
</table>

Figure C.3 — Example of P-QRS-T Group

In the case of single peak P wave, first peak part of P wave is only used. In the case of double-peaked pattern, for the first P wave (in general, right atrioventricular component), the first peak is used and for the rear P wave (in general, left atrioventricular component), the P wave second peak is used. In the case of positive P and negative P or negative P and positive P, for the first P wave is used the first P and for rear P wave is used as second P (see Figure C.4).



Key

1 P wave

2 P2 wave

3 first peak of P wave

4 second peak of P wave

Figure C.4 — P wave

C.5 Classification code

Each classified point is represented in Table C.3 on the first element of MWF_EVT.

Table C.3 — Classification code

Reference ID	CODE		English name
	DEC	HEX	
MWF_ECG_DOMT	55808	DA00	Dominant beat
MWF_ECG_AVBEAT	56320	DC00	Averaging beat
MWF_ECG_P_WAVE	35328	8A00	P wave
MWF_ECG_P2_WAVE	35840	8C00	P2 wave
MWF_ECG_P1_PEAK	36352	8E00	P wave first peak
MWF_ECG_P2_PEAK	36864	9000	P wave second peak
MWF_ECG_PP_WAVE	37376	9200	P’ wave (Retrograde)
MWF_ECG_PP2_WAVE	37888	9400	P’2 wave
MWF_ECG_PP1_PEAK	38400	9600	P’ wave first peak
MWF_ECG_PP2_PEAK	38912	9800	P’ wave second peak
MWF_ECG_QRS_COMPLEX	41472	A200	QRS complex
MWF_ECG_QRS_PEAK	41984	A400	QRS peak
MWF_ECG_Q_WAVE	43008	A800	Q wave

Table C.3 *(continued)*

Reference ID	CODE		English name
	DEC	HEX	
MWF_ECG_Q_PEAK	43520	AA00	Q wave peak
MWF_ECG_R_WAVE	44032	AC00	R wave
MWF_ECG_R_PEAK	44544	AE00	R wave peak
MWF_ECG_R2_WAVE	45056	B000	R' wave
MWF_ECG_R2_PEAK	45568	B200	R' wave peak
MWF_ECG_R3_WAVE	46080	B400	R" wave
MWF_ECG_R3_PEAK	46592	B600	R" wave peak
MWF_ECG_S_WAVE	47104	B800	S wave
MWF_ECG_S_PEAK	47616	BA00	S wave peak
MWF_ECG_S2_WAVE	48128	BC00	S' wave
MWF_ECG_S2_PEAK	48640	BE00	S' wave peak
MWF_ECG_S3_WAVE	49152	C000	S" wave
MWF_ECG_S3_PEAK	49664	C200	S" wave peak
MWF_ECG_QRS_NOTCH	50176	C400	Notch
MWF_ECG_DELTA	42496	A600	Delta
MWF_ECG_T_END	51712	CA00	T wave end
MWF_ECG_T_PEAK	52224	CC00	T wave peak
MWF_ECG_T2_END	52736	CE00	T' wave end
MWF_ECG_T2_PEAK	53248	D000	T' wave peak
MWF_ECG_U_END	53760	D200	U wave end
MWF_ECG_U_PEAK	54272	D400	U wave peak
MWF_ECG_STJ	50688	C600	ST-j
MWF_ECG_ST	51200	C800	ST
WMF_ECG_J_WAVE	39424	9A00	J wave
MWF_ECG_H_WAVE	40448	9E00	His bundle wave
MWF_ECG_FIDUCIAL	33792	8400	Fiducial point
MWF_ECG_ISOELECTRIC	33280	8200	Isoelectric point
MWF_ECG_UN_PACING	34048	8500	Pacing pulse (unknown)
MWF_ECG_A_PACING	34304	8600	Atrial pacing pulse
MWF_ECG_V_PACING	34816	8800	Ventricular pacing pulse
MWF_ECG_CAL	55296	D800	Calibration

C.6 Measurement value (measurement value with no lead designation)

Table C.4 shows the values measured by total leads.

Table C.4 — Measurement value (no lead designation) code table

Reference ID	CODE		English name
	DEC	HEX	
MWF_ECG_HEART_RATE	32769	8001	Heart rate
MWF_ECG_VPC_MIN	32778	800A	VPC rate per min
MWF_ECG_VPC_HOUR	32780	800C	VPC rate per hour
MWF_ECG_TIME_PD_RR	32770	8002	RR interval
MWF_ECG_ANGLE_P_FRONT	32772	8004	P wave axis
MWF_ECG_ANGLE_QRS_FRONT	32774	8006	QRS axis
MWF_ECG_ANGLE_T_FRONT	32776	8008	T wave axis
MWF_ECG_ANGLE_T_PP	32782	800E	PP interval

C.7 Measurement value (allowed to designate for each lead)

In the event that the measurement value differs for each lead and all leads are standardized, the measurement value shall be specified. In the event that Leads III, aVL, etc. are values calculated from lead composition, the measurement value can be described by designating the virtual channel, but to be simple, it can be encoded by the present rules (lead name designation). In the case of lead code 0, it is interpreted to be no lead designation (see Figure C.5). Such measurement values are shown in Table C.5. Where still more detailed description is required, it is found by operation from the waveform classification point and sampling information.

16	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1
Measurement value code								Lead code							

Figure C.5 — Measurement value code composition

Table C.5 — Measurement value table for each lead

Reference ID	CODE		English name
	DEC	HEX	
MWF_ECG_TIME_PD_P	57472	E080	P width
MWF_ECG_AMPL_P1	57600	E100	P1 amplitude
MWF_ECG_AMPL_P2	57728	E180	P2 amplitude
MWF_ECG_TIME_PD_PQ	57856	E200	PQ interval
MWF_ECG_AREA_P_WAV	59776	E980	P Area
MWF_ECG_TIME_PD_Q	57984	E280	Q duration
MWF_ECG_AMPL_Q	58112	E300	Q amplitude
MWF_ECG_TIME_PD_QRS	58240	E380	QRS duration
MWF_ECG_TIME_PD_R	59904	EA00	R duration
MWF_ECG_AMPL_R	58368	E400	R amplitude
MWF_ECG_TIME_PD_R2	60032	EA80	R2 duration
MWF_ECG_AMPL_R2	59392	E800	R2 amplitude
MWF_ECG_TIME_PD_S	60160	EB00	S duration
MWF_ECG_AMPL_S	58496	E480	S amplitude
MWF_ECG_TIME_PD_S2	60288	EB80	S2 duration
MWF_ECG_AMPL_S2	59520	E880	S2 amplitude
MWF_ECG_AMPL_STJ	58624	E500	STj